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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,301

07/10/2003

Yoav Kimchy

25854

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67801

7590

04/28/2010

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EXAMINER

CHAO, ELMER M

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3737

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/616,301	Applicant(s) KIMCHY ET AL.	
	Examiner ELMER CHAO	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/18/2010; 10/4/2009; 8/16/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgement is made of the Appeal Brief filed 1/19/2010. Examiner has determined to reopen prosecution.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title must be different from the title of the patented parent case.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on 1/18/2010, 10/4/2009, & 8/16/2009 were filed after the mailing date of the final office action on 7/15/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

Art Unit: 3737

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. **Claims 1-4, 6, 7, and 16-19** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 60-64, 81, 82, 91, 92, 98, 109-117, and 120-125 of copending Application No. 10/240,239 in view of Houzego et al. (U.S. 6,632,216 B2). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Application 10/240,239 disclose all of the required limitations except for circuitry to determine location and orientation of the probe. However, Houzego et al. teach a capsule probe with location and orientation tracking (col. 1, lines 40-44). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include circuitry to detect location and orientation in order to determine the exact location that the image is being obtained (col. 1, lines 40-44).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. **Claims 1 and 16-19** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40, 46, 48, 49,

Art Unit: 3737

58, 64, and 65 of copending Application No. 11/132,320 in view of Houzego et al. (U.S. 6,632,216 B2). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Application 11/132,320 disclose at least all of the required limitations except for circuitry to determine location and orientation of the probe. However, Houzego et al. teach a capsule probe with location and orientation tracking (col. 1, lines 40-44). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include circuitry to detect location and orientation in order to determine the exact location that the image is being obtained (col. 1, lines 40-44).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 1-4, 6, 7, and 16-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassan in view of Barrett et al (U.S. 4,595,014), further view of Glukhovsky (U.S. 6,584,348), and further in view of Schentag (U.S. 5,279,607).

Regarding claims 1, 2, 6, and 16-19, Hassan teaches "A Radiotelemetry Pill for the Measurement of Ionising Radiation using a Mercuric Iodide Detector" (title).

Art Unit: 3737

Regarding claim 1, Hassan teaches that “the radiation pill consists of a mercuric iodide crystal, amplifier, transmitter, and a 1.35V battery” (last paragraph, pg. 303). Hassan teaches of “the pill’s plastic encapsulation” (last paragraph, pg. 306). Regarding claim 2, Hassan teaches that the “radiopill can also serve as a general purpose telemetric γ -ray detector” (last paragraph, pg. 302). Hassan teaches that “The radiopill was also tested as a beta detector” (first paragraph, pg. 307).

Hassan substantially discloses all the limitations as discussed above. Hassan does not disclose an ingestible device with a plurality of nuclear-radiation detectors arranged on the external surface of the ingestible device. However, Barrett ('014) teaches a “nuclear radiation probe that includes multiple radiation detectors (C3, L51-53). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Hassan to create an ingestible device with a plurality of nuclear-radiation detectors. Such a modification would help increase the area imaged are by not requiring the device to rotate fully in order to image the surrounding area (C3, L62-67). Glukhovsky ('348) teaches a capsule with electrode probes protruding out from openings of the capsule (Figure 2A). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Hassan in view of Barrett ('014) to include a plurality of nuclear radiation detectors arranged around the external surface of the ingestible device. Such a modification would improve the sensitivity of the probes by not enclosing them by an encapsulation that could potentially attenuate the detectable radiation.

Hassan, Barrett ('014), and Glukhovsky ('348) teach the limitations as discussed above but fail to explicitly teach the system comprising circuitry adapted to determine the location of the ingestible device and reconstruct the diagnostic image based on the location. However, Schentag ('607) teach means necessary to perform the wireless tracking and signal transmission of telemetry capsules (col. 2, line 64 – col. 3, line 28; col. 8, line 66 - col. 9, line 38). Additionally, Barrett ('014) do teach a radiation imaging probe and a system capable of detecting the location of the probe and to reconstruct an image based on the location (abstract; col. 1, line 63 – col. 2, line 15). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Hassan, Barrett ('014), and Glukhovsky ('348) to include circuitry capable of sensing location and reconstructing a diagnostic image based on said location in order to allow for the position and the strength of the source of a tumor to be determined in the presence of background radiation (for motivation see Barrett ('014) col. 2, lines 16-22).

Hassan, Barrett ('014), Glukhovsky ('348), and Schentag ('607) teach the limitations as discussed above but fail to explicitly teach the system comprising circuitry adapted to determine the orientation of the ingestible device. However, Hassan does suggest the need for orienting the ingestible device (see page 306, first paragraph under the 'Performance' section). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Hassan, Barrett ('014), Schentag ('607), and Glukhovsky ('348) to include circuitry capable of sensing the orientation of the ingestible device in order to improve detection of radiation by the pill

Art Unit: 3737

when the source is angled behind the battery side of the detector (for motivation see page 306, first paragraph under the 'Performance' section).

Regarding **claims 3 and 4**, Hassan teaches that “the sensitivity of the pill has been found for $^{99}\text{Tc}^m$, ^{131}I and ^{32}P ” (abstract).

Regarding **claim 7**, Hassan does not teach the radiotelemetry pill with a collimator, nor does it even hint at the mercuric iodide crystal being collimated.

9. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hassan in view of Barrett et al., further in view of Glukhovsky and Schentag, and further in view of Zhang et al. (Society of Nuclear Medicine, June 2000). Hassan, Barrett et al., and Glukhovsky substantially disclose all the limitations as discussed above. They do not disclose an ingestible device arranged as a Compton camera. However, Zhang teaches a transrectal imaging probe based on Compton camera techniques (No. 68, second sentence). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the invention to include a Compton camera probe as evidenced by Zhang. Such a modification would allow the ingestible device to have high sensitivity and high resolution (No. 68, second sentence).

Response to Arguments

1. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

2. Applicant's arguments filed 9/24/2008 have been fully considered but they are not persuasive.

Examiner notes that the new grounds of rejection is similar to those sent out in the office action dated 6/25/2008 and Examiner will therefore respond to the arguments filed 9/24/2008.

Applicants argue that "Hassan describes its pill as "a small inexpensive radiation pill". It is accordingly submitted that Hassan would not add circuitry which will make the pill more complex and will not add any utility to it.". Examiner notes that this is not a valid argument against the obviousness of Applicants' invention. Hassan is the primary reference published in 1978. Its ubiquitous disclosure of "a small inexpensive radiation pill" does not preclude one of ordinary skill in the art from adding more complex features to the pill. Examiner notes that even Applicants' invention can be considered "a small inexpensive radiation pill". Applicants are advised not to confuse expense with complexity, and to keep in mind that expense is a subjective measure.

As Examiner responded in the Non-Final rejection mailed 10/7/2008:

" Regarding Applicants' arguments with respect to page 6, paragraph 2, of the Remarks filed 9/24/2008, Examiner feels that it is necessary to correct Applicants' statement regarding what the Examiner agreed with during the phone interview conducted on 9/4/2008. During the interview, Examiner was given a description of a highly detailed invention that was beyond the language of claim 1. This description included at least *functional* differences between the intended function of the invention and those of the references. Examiner only provided

Applicants with the opinion that the concept *as described* by the representative over the phone (Mr. Fenster) *may* be novel over the former rejection filed 6/25/2008. Examiner also stated that a further search and consideration would be required. Please refer to the interview summary record filed 9/30/2008.”

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELMER CHAO whose telephone number is (571)272-0674. The examiner can normally be reached on Mon-Thurs 11am-9pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/

Application/Control Number: 10/616,301
Art Unit: 3737

Page 10

Supervisory Patent Examiner, Art
Unit 3737

/E. C./
Examiner, Art Unit 3737